

REMARKS

I. STATUS OF THE CLAIMS

Claims 1, 5, 8-10, 12-29, 31-40, 44-49, 51-56, 58-62, 66-86 and 88-91 are pending.

Claims 2-4, 6, 7, 11, 30, 41-43, 50, 57, 63-65 and 87 were previously canceled without prejudice against their reintroduction into this or one or more timely filed continuation, divisional or continuation-in-part applications.

Claims 5, 19-40, 44-62 and 66-91 have been withdrawn from consideration as being drawn to non-elected embodiments.

With this Amendment, claims 1, 5, 23 and 76-80 are amended. Thus, after entry of this Amendment, claims 1, 5, 8-10, 12-29, 31-40, 44-49, 51-56, 58-62, 66-86 and 88-91 remain pending, with claims 1, 8-10 and 12-18 currently under consideration. The amendments of the claims and the various rejections raised in the Office Action are discussed in more detail, below.

II. AMENDMENTS

Claims 1 and 44 are amended to correct an omission made when these claims were amended in Applicants' response filed 23 May 2011. In that response, claims 1 and 44 should have been amended to incorporate the limitations of original claims 3 and 4, but only a part of claims 3 and 4 were actually incorporated.

Claim 5 is amended for proper dependency.

Claims 23 and 76-80 are amended to remove reference to the ORFs of genes 7, 46, 48 and 66.

No new matter is added by way of the amendments presented herein.

III. CLAIM REJECTION UNDER 35 USC §112

Claims 1, 8-10 and 12-18 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amendment of claims 1 and 44 corrects an omission made when these claims were amended with Applicants' response filed 23 May 2011. In that response, claims 1 and 44 should have been amended to incorporate the limitations of original claims 3 and 4, but only a part directed to flanking regions and not in the ORF were were actually incorporated. The

present amendment incorporates the missing subject matter, and obviates this rejection.

Applicants respectfully request reconsideration and withdrawal of the rejection.

IV. CLAIM REJECTION UNDER 35 USC §103

Claims 1, 8-10 and 12-18 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Horsburgh *et al.* (US Patent 6,277,621 B I, hereinafter, "Horsburgh") in view of Cohen *et al.* (PNAS USA, 1993,90:7376-7380, hereinafter, "Cohen") and Mori *et al.* (US Patent Application Publication 20080226677, filed May 12,2004, hereinafter, "Mori").

Horsburgh describes recombination "in the ORF region" of the gene, and does not disclose or relate to insertion of the BAC sequence into the flanking region of a non-essential gene. Mori is cited for its teaching of "the use of BAC vectors to express viral genes, as well as the use of recombinant protein dependent recombinant sequences" and the Examiner states that the skilled artisan "would have been motivated to use such sequences in order to control the site of recombination." (Office Action at page 5). Cohen is cited for its teaching of inserting a BAC sequence into the non-essential gene region of ORF13, in attempt to cure the deficiencies of Horsburgh and Mori. However, Cohen is irrelevant to the present claims, as Cohen is directed to the production of an ORF13-deficient virus, disrupting its function with the purpose of analyzing the function of ORF13. Cohen merely discloses that ORF 13 is a non-essential gene, but fails to disclose or even conceive of insertion of a BAC vector into a region in the ORF of gene 13, or a region flanking the ORF of gene 13 as an appropriate region for *avoiding* disruption of the function of the region into which the BAC vector is inserted, for production of an attenuated recombinant live varicella virus and vaccine thereof. Moreover, not only did Cohen not conceive of producing an attenuated recombinant live varicella virus and vaccine thereof, but Cohen is completely silent with respect to confirming production of expression constructs comprising a BAC vector. One of the advantages of the presently claimed subject matter is that insertion of a BAC vector into a non-essential gene or its flanking region *avoids* disruption of the function of the region into which the BAC vector is inserted (*i.e.* gene 13 following insertion maintains its function).

Applicants did not identify just one non-essential gene, but rather, a region was identified where many non-essential genes are present, and that region was appropriate for inserting BAC vector such that the BAC vector can avoid disruption of the function of the

region. Applicants recognized that inserting BAC vector sequences into these non-essential gene regions allows the cloning of a full length genome without deleting an essential ORF or function, while avoiding any adverse effects upon viral reconstitution by BAC sequence insertion, even though the BAC sequence insertion may have adverse effects on expression of genes around the insertion region. By way of another example, the present specification specifically discloses inserting BAC vector into intergenic region of ORF11/ORF12, as part of a region where many non-essential genes are present, and thus, the non-essential gene regions are appropriate for inserting a BAC vector. Such results were in no way expected by, and would not have been obvious to, those skilled in the art.

The Examiner's assertion appears to be solely based on hindsight recognition of Applicants' own disclosure. No reasoning has been provided for how or why the skilled artisan would have chosen, of all the possible combinations of sequences taught by Horsburgh, Mori, or Cohen, Applicants' particularly claimed sequences in a region in the ORF of or in a region flanking the ORF of a non-essential gene. None of the cited references teach or suggest inserting a BAC sequence into an ORF of or in a region flanking the ORF of gene 13.

The cited references, alone or in combination fail to conceive of the use of Applicants' specified ORFs or regions flanking the ORFs of these particular non-essential genes of an Oka strain for insertion of BAC vector sequences and production of an attenuated recombinant live varicella virus and vaccine thereof, having the advantageous effects demonstrated by Applicants' claimed subject matter. Applicants' claims are novel and non-obvious.

Applicants respectfully request reconsideration and withdrawal of this rejection.

V. DOUBLE PATENTING

Claims 1, 8-10 and 12-18 remain provisionally rejected on the ground of non-statutory obviousness-type double patenting as allegedly being unpatentable over claims 1, 4, 11-17, 24 and 25 of co-pending Application No. 12/094,757.

Applicants again respectfully request that this provisional obviousness-type double-patenting rejection be held in abeyance until patentable subject matter is found in one of the co-pending applications, or until the other rejections in the present case are overcome and the claims of this case are otherwise in condition for allowance.

Again, the rejection is provisional because the claims of the cited applications have not been patented. It is improper for the Examiner to maintain a provisional obviousness-type double-patenting rejection based on claims that have not been allowed or issued in a patent. Until patentable subject matter is found in the applications not yet granted and serving as the basis of this provisional rejection, the claims of the instant application should be considered on their merits.

Thus, Applicants again respectfully request withdrawal of this provisional obviousness-type double-patenting rejection, and request that the claims of the instant application be considered on their merits.

Applicants reserve the right to file a terminal disclaimer in the event that it is deemed necessary in a later stage of prosecution.

VI. CONCLUSION

In view of the foregoing, Applicants submit that the pending claims are in condition for Allowance. A Notice of Allowance is respectfully requested.

No fees, beyond the fee for a one-month extension of time, are believed to be due in connection with this Amendment. However, the Commissioner is authorized to charge any additional fees that may be required, or credit any overpayment, to King & Spalding LLP Deposit Account No. 50-4616.

If a telephone conference would expedite the prosecution of the subject application, the Examiner is requested to call the undersigned at (650) 590-1932.

Respectfully submitted,
KING & SPALDING LLP

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